510(k) Summary
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MAY 17 2010

EasyGlide Ltd.
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Kfar Truman, 73150
Israel

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Official Contact: Izhak Fabian - CEO

Proprietary or Trade Name: ClearJet

Common/Usual Name: Endoscope accessory

Classification Name/Code: KOG - endoscope and/or accessories
CFR 876.1500

Device: ClearJet

Predicate Devices: K091305 – Easy Glide – ClearPath
K0070420 – US Endoscope BioShield

Device Description:
The proposed ClearJet adapter is intended to perform irrigation through the working channel of an endoscope by providing a means to control the fluid irrigation with the cleared ClearPath control unit.

The ClearJet's is design to improve procedure reliability by improving visualization during endoscopic procedures. The ClearJet utilizes an irrigation / biopsy valve adapter enabling attachment to an endoscope's working channel port for the purpose of performing a colon or stomach wash.

The ClearJet is composed of two major units:

- A disposable Irrigator and
- A Control cabinet

It is designed to fit the standard endoscope models of Pentax, Olympus, and Fuijinon.

Indications for Use:
The ClearJet is an irrigation / biopsy adapter and irrigation tubing set used to cover the opening to the biopsy / suction / irrigation channel of standard endoscopes. It provides access for endoscopic device passage and exchange, helps maintain sufflation, minimizes leakage of biomaterial from the biopsy port throughout the endoscopic procedure, and provides access for irrigation.

It is for use only by trained medical personnel located in hospitals, clinics, and doctors' offices.

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Patient Population:
Individuals undergoing procedures endoscopic procedures.

Environment of Use:
Hospitals, clinics, and doctors' offices.

Performance Testing Summary

We performed comparative flow and pressure testing to confirm that the ClearJet with the ClearPath controller operate within the predicate specifications, which was conformed.

Summary of substantial equivalence:

We have compared the ClearJet to the listed predicates for:

Indications –
- Identical to predicate for use as a multiple port adapter to the working channel of endoscopes – K070420 – US Endoscopy Bio-Shield
- Identical to the predicate for use as an irrigation accessory – ClearPath Irrigator and Controller – K091305 – EasyGlide ClearPath

Technology –
- Identical technology used –in basic materials and use of a peristaltic pump for control and delivery of irrigation fluids – K091305 – EasyGlide ClearPath
- Identical technology of a multiple port adapter for connecting to and accessing the working channel of an endoscope – K070420 US Endoscopy Bio-Shield

Materials –
- The materials in fluid contact are identical to the predicate device, ClearPath K091305 or have been tested per ISO 10993.

Environment of Use –
- Identical to predicates – K091305 – EasyGlide ClearPath and K070420 – US Endoscopy Bio-Shield

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

EasyGlide Ltd
% Mr. Paul Dryden
President
ProMedic, Inc.
24301 Woodsage Drive
BONITA SPRINGS FL 34134

MAY 17 2010

Re: K101094
Trade/Device Name: ClearJet
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: ODC
Dated: April 18, 2010
Received: April 20, 2010

Dear Mr. Dryden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K101094 (To be assigned)

Device Name: ClearJet

Indications for Use:

The ClearJet is an irrigation / biopsy adapter set used to cover the opening to the biopsy / suction / irrigation channel of Pentax, Olympus and Fujinon endoscopes. It provides access for endoscopic device passage and exchange, helps maintain sufflation, minimizes leakage of biomaterial from the biopsy port throughout the endoscopic procedure, and provides access for irrigation.

It is for use only by trained medical personnel located in hospitals, clinics, and doctors' offices.

Prescription Use XX (Part 21 CFR 801 Subpart D) **or** **Over-the-counter use __** (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K101094